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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/520,685

05/27/2005

Allan Otto Fog Lihme

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EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

10/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,685

Applicant(s)

LIHME ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1, 3-12 and 19 are drawn to an extracorporeal adsorption method for removing harmful substances responsible of inducing sepsis caused by Gram-negative in a mammal, said extracorporeal adsorption method being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for the LPS portion of said Gram-negative bacteria, said method comprising treating blood obtained from said mammal by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed.

II. Claims 2 and 14 are drawn to an extracorporeal adsorption method for removing harmful substances responsible of inducing sepsis caused by Gram-negative or Gram-positive bacteria in a mammal, said extracorporeal adsorption method being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for: i) the LPS portion of said Gram-negative bacteria, and/or ii) Gram-positive bacteria or harmful substances derived from said Gram-positive bacteria and the use of an adsorption medium for the preparation of a therapeutic adsorption column assembly for the therapeutic treatment of sepsis caused by Gram-negative or Gram-positive bacteria in a mammal by extracorporeal adsorption, said adsorption column assembly comprising (a) a vessel for continuous obtaining blood from said mammal, (b) a column and the adsorption medium, the sedimented volume of said adsorption medium being at the most 80% of the volume of the column, said adsorption medium being characterized by carrying an affinity specific molecule with a specific affinity for: i) the LPS portion of said Gram-negative bacteria, and/or ii) Gram-positive bacteria or harmful substances derived

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from said Gram-positive bacteria, said column is treating the obtained blood by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the adsorption medium is formed, and (c) another vessel which continuously delivers blood back to the patient..

III. Claims 13, 15, 17-18 and 20-26 are drawn to the use of an adsorption medium for the preparation of a therapeutic adsorption column assembly for the continuous therapeutic treatment of sepsis caused by Gram-negative bacteria in a mammal by extracorporeal adsorption, said adsorption column assembly comprising (i) a vessel for continuous obtaining blood from said mammal, (ii) a column comprising the adsorption medium, the sedimented volume of said adsorption medium being at the most 80% of the volume of the column, said adsorption medium being characterized by carrying an affinity specific molecule with a specific affinity for the LPS portion of said Gram-negative bacteria, said column is treating the obtained blood by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the adsorption medium is formed, and (iii) another vessel which continuously delivers blood back to the patient.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The adsorption medium recited in group III can be used with methods other than those recited in groups I or II. For instance, the adsorption medium can be used in a method to treat sepsis or for the removal of small water-soluble substances. Therefore, the adsorption medium's special technical feature is comprised within the medium and not within the methods steps; therefore the groups lack the same or corresponding technical feature.

Groups I and III, is drawn to an unrelated inventions because it use, function and effect are patentably distinct in comparison to the other groups. Group I has a different special technical feature when compared to the claims of Group III; because the recited components the adsorption column assembly are the special technical features.

Theses special technical features are comprised within their structural differences of the

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assembly. Accordingly, the groups lack a corresponding technical feature. Finally, groups I and II are unrelated and do not share a special technical feature because each method has a separate and distinct purpose with separate and distinct final outcomes and different particles characterized by their carrying affinity with specific affinity for the LPS portion of said Gram-negative bacteria, and/or ii) Gram-positive bacteria or harmful substances derived from said Gram-positive bacteria. Therefore, there is no corresponding special technical feature between the groups I and II and III.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
September 29, 2007


MARK NAVARRO
PRIMARY EXAMINER